Complete if Known Substitute for form 1449A/PTO Application Number 10/731,604 Filing Date December 8, 2003 INFORMATION DISCLOSURE First Named Inventor Karimisetty, Srikanth STATEMENT BY APPLICANT Art Unit 2168 (Use as many sheets as necessary) **Examiner Name** OMOSEWO, OLUBUSOLA Attorney Docket Number 021756-002100US Sheet

| | Cit | | U.S. PATENT DO | | Deeps Columns Lines Mines |
|---|--------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No.1 | Document Number Number Kind Code ^{2 (f known)} | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| M | 1 | 5,434,917 | 07-18-1995 | Naccache et al. | |
| 1 | 2 | 5,504,818 | 04-02-1996 | Okano | |
| 1; | 3 | 5,978,475 | 11-02-1999 | Schneier et al. | |
| 1 | 4 | 6,295,513 | 09-25-2001 | Thackston | |
| 1 | 5 | 6,366,934 | 04-02-2002 | Cheng et al. | |
| | 6 | 6,796,489 | 09-28-2004 | Slater et al. | |
| $\neg \vdash$ | 7 | 6,807,633 | 10-19-2004 | Pavlik | |
| 7 | 8 | 6,820,082 | 11-16-2004 | Cook et al. | |
| -/- | 9 | 6,928,396 | 08-09-2005 | Thackston | |
| 1 | | 6,959,281 | 10-25-2005 | Freeling et al. | |
| / | 11 | 6,978,366 | 12-20-2005 | Ignatchenko et al. | |
| <i> </i> | | 6,983,423 | 01-03-2006 | Dvorak et al. | |
| | 13 | 6,990,585 | 01-24-2006 | Maruyama et al. | |
| | 14 | 7,039,805 | 05-02-2006 | Messing | |
| | 15 | 7,039,807 | 05-02-2006 | Spitz | *************************************** |
| / | <u> </u> | 7,089,235 | 08-08-2006 | Dettinger et al. | |
| -/- | | 7,093,133 | 08-15-2006 | Hopkins et al. | • |
| - | | 7,136,873 | 11-14-2006 | Smith et al. | |
| | 19 | 7,143,103 | 11-28-2006 | Zisman et al. | |
| | 20 | 7,146,500 | 12-05-2006 | Hawkins et al. | |
| | 21 | 7,165,179 | 01-16-2007 | Maruyama et al. | |
| $\neg \vdash$ | 22 | 7,174,328 | 02-06-2007 | Stanoi et al. | |
| $\neg \!$ | 23 | 7,185,192 | 02-27-2007 | Kahn | |
| | | 7,228,300 | 06-05-2007 | Lei et al. | |
| \neg | | 2001/0002485 | 05-31-2001 | Bisbee et al. | |
| 1 | 26 | 2001/0039545 | 11-08-2001 | Nishizawa | |
| 1 | 27 | 2002/0010764 | 01-24-2002 | Spicer | • |
| 1 | 28 | 2002/0040431 | 04-04-2002 | Kato et al. | |
| 1 | 29 | 2002/0049670 | 04-25-2002 | Moritsu et al. | |
| 1 | 30 | 2002/0156756 | 10-24-2002 | Stanley et al. | |
| _/_ | 31 | 2002/0157006 | 10-24-2002 | Narishima et al. | |
| | 32 | 2003/0009295 | 01-09-2003 | Markowitz et al. | |
| | 33 | 2003/0065936 | 04-03-2003 | Wray | |
| \neg | 34 | 2003/0078880 | 04-24-2003 | Alley et al. | |
| d) | 35 | 2003/0131241 | 07-10-2003 | Gladney | |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. There office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. For indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

| Subs | titute for form 1449A/PTO | | | Complete if Known | | | |
|------------------------|---------------------------|--------|------|------------------------|-----------------------|--|--|
| | · | | | Application Number | 10/731,604 | | |
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| | FORMATION DISC | | | First Named Inventor | Karimisetty, Srikanth | | |
| STATEMENT BY APPLICANT | | | | Art Unit | 2168 | | |
| | (Use as many sheets as ne | cessar | y) | Examiner Name | OMOSEWO, OLUBUSOLA | | |
| Sheet | 2 | of | 4 | Attorney Docket Number | 021756-002100US | | |

| | | | U.S. PATENT DO | CUMENTS | |
|-----------------------|--------------|--|--------------------------------|--|---|
| Examiner Initials* | Cite No.1 | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| A | <u> </u> | Number Kind Code ^{2(f known)} | | | |
| W | 36 | 2003/0149608 | 08-07-2003 . | Kall etal. | |
| 7 | 37 | 2003/0150908 | 08-14-2003 | Pokorny et al. | |
| | 38 | 2003/0177041 | 09-18-2003 | Millican et al. | |
| | 39 | 2003/0196108 | 10-16-2003 | Kung | |
| | 40 | 2003/0200130 | 10-23-2003 | Kall etal. | |
| | 41 | 2004/0039706 | 02-26-2004 | Skowron et al. | |
| | 42 | 2004/0068757 | 04-08-2004 | Heredia | |
| | 43 | 2004/0123108 | 06-24-2004 | Winkler et al. | |
| | 44 | 2004/0236660 | 11-25-2004 | Thomas et al. | |
| | 45 | 2005/0044369 | 02-24-2005 | Anantharaman | |
| | 46 | 2005/0102158 | 05-12-2005 | Maeda, Chris | • |
| | 47 | 2005/0108153 | 05-19-2005 | Thomas et al. | |
| | 48 | 2005/0132201 | 06-16-2005 | Pitman et al. | |
| V | 49 | 2005/0240770 | 10-27-2005 | Lane et al. | |

| | FOREIGN PATENT DOCUMENTS | | | | | | | | | | |
|-----------------------|--------------------------|---|--------------------------------|--|---|----------------|--|--|--|--|--|
| Examiner Initials* | Cite No. | Foreign Patent Document Country Code ³ Number Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ | | | | | |
| | | | | | | | | | | | |

Examiner Signature Date Considered 7/44/67

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| Substitute | for form 1449B/PTO | | | Complete if Known | | | |
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| | | | | Application Number | 10/731,604 | | |
| INFO | RMATION DIS | CLOS | URE | Filing Date . | December 8, 2003 | | |
| STAT | TEMENT BY A | PPLIC | ANT | First Named Inventor | Karimisetty, Srikanth | | |
| | | | | Art Unit | 2168 | | |
| | (Use as many sheets as i | necessary) | | Examiner Name | OMOSEWO, OLUBUSOLA | | |
| Sheet | 3 | of | 4 | Attorney Docket Number | 021756-002100US | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | | | | | |
|---------------------------------|--|---|--------------------|---------------------------|--|--|--|--|--|
| Examiner Initials * | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | | | | | | |
| Am | 50 | BERTINO et al. "Integrating XML and Databases" IEEE | Internet Con | nputing July-Aug 2001 | | | | | |
| | 51 | CHUEH et al., "An XML Portable Chart Format," 1998, | Proc AMIA S | ymp., pp. 730-734. | | | | | |
| · \ | 52 | FDA, Guidance for Industry Part 11, Electronic Records Application, Aug. 2003. | ; Electronic S | Signatures - Scope and | | | | | |
| | 53 | MATHIESON, "Implementing Oracle Workflow," Europe Presentation pages 1-11 | ean Oracle Us | ser Group 1999 | | | | | |
| / | 54 | MEEHAN, "Deploying Hummingbird Document and Records Management Products to Comply with 21 CFR Part 11: Electronic Records; Electronic Signatures," April 2003, Hummingbird. | | | | | | | |
| | 55 | MUIRHEAD, "Impact of 21 CFR Part 11 on clinical labo American Clinical Laboratory, pp. 33-34. | ratories: An o | overview," Aug. 2001, | | | | | |
| | 56 | NOFERI et at. "Information Age Audits" BioPharm Jan | 2002 pgs 35- | 39 and 50 | | | | | |
| | 57 | ORACLE, "Oracle Workflow Release 2.6.2 Business Ev Guidelines October 2001 26 pages | vent System a | and PL/SQL Development | | | | | |
| | 58 | ORACLE, "Question & Answer Document for Oracle Ap | psworld" Jan | nuary 19-22, 2003 pg 1-81 | | | | | |
| | ORACLE, Oracle Life Sciences Platform Feature Summary, Feb. 2003, Oracle Corp. | | | | | | | | |
| 1 | 60 | PAPAZOGLOU, "The World of e-Business: Web-Servic Transactions" WES 2002, LNCS 2512, pp 153-173,200 | | s, and Business | | | | | |
| Examiner Signature | In | hi | Date Considered | 7/24/07 | | | | | |

EXAMINER: Initial if elerence considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| | Substitute fo | or form 1449B/PTO | | | Complete if Known | | | |
|---|-----------------------------------|-------------------|-------|-----|------------------------|-----------------------|--|--|
| | | | | | Application Number | 10/731,604 | | |
| | INFO | RMATION DIS | CLOS | URE | Filing Date | December 8, 2003 | | |
| | STAT | EMENT BY A | PPLIC | ANT | First Named Inventor | Karimisetty, Srikanth | | |
| 1 | | | | | Art Unit | 2168 | | |
| | (Use as many sheets as necessary) | | | | Examiner Name | OMOSEWO, OLUBUSOLA | | |
| | Sheet | 4 | of | 4 | Attorney Docket Number | 021756-002100US | | |

| NON PATENT LITERATURE DOCUMENTS | | | | | | | | |
|---------------------------------|--------------------------|---|-----|--|--|--|--|--|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T 2 | | | | | |
| Am | 61 | SmarTeam, SMARTEAM - FDA Compliance Configuration (SFA), IBM/SmarTeam, Sep. 2003. | | | | | | |
| 7 | 62 | SmarTeam, SMARTeam TM FDA Compliance Technical Paper Functional Compliance With FDA Rule 21 CFR Part 11, July 2002, SMARTEAM Corp. | | | | | | |
| | 63 . | STEMBER, LABTrack: Introducing a legal electronic lab notebook, 221st National Meeting, American Chemical Society, Division of Chemical Information. | | | | | | |

| | | | | | , | 1 |
|-----------------------|----------------------|----|--------------------|---|-----|-----|
| Examiner Signature | 7 | M: | Date Considered | 7 | 24/ | 107 |
| | \boldsymbol{r} | | | | | |

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